

Message

From: Lin, Chuenfung (NIH/OD/ORF) [E] [chuenfung.lin@nih.gov]
Sent: 4/12/2018 12:24:48 PM
To: Bahadori, Tina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7da7967dcafb4c5bbc39c666fee31ec3-Bahadori, Tina]
Subject: RE: today's Inside EPA article on the NAS report

Remember the old saying: *a big tree attracts the wind*. CF

Chuenfung Lin, AIA | NCARB
p: 301.496.8778 | c: Personal Matters / Ex. 6 | e: chuenfung.lin@nih.gov

From: Bahadori, Tina [mailto:Bahadori.Tina@epa.gov]
Sent: Thursday, April 12, 2018 8:08 AM
To: Lin, Chuenfung (NIH/OD/ORF) [E] <chuenfung.lin@nih.gov>
Subject: Fwd: today's Inside EPA article on the NAS report

Begin forwarded message:

From: "Soto, Vicki" <Soto.Vicki@epa.gov>
Date: April 12, 2018 at 7:25:12 AM EDT
To: "Bahadori, Tina" <Bahadori.Tina@epa.gov>, "Thayer, Kris" <thayer.kris@epa.gov>, "Shams, Dahnish" <Shams.Dahnish@epa.gov>, "Avery, James" <Avery.James@epa.gov>, "Kraft, Andrew" <Kraft.Andrew@epa.gov>, "Glenn, Barbara" <Glenn.Barbara@epa.gov>, "Radke-Farabaugh, Elizabeth" <radke-farabaugh.elizabeth@epa.gov>
Subject: today's Inside EPA article on the NAS report

<https://insideepa.com/daily-news/nas-praises-epas-efforts-improve-iris-underscoring-congress-action>

Daily News

NAS Praises EPA's Efforts To Improve IRIS, Underscoring Congress' Action

April 11, 2018

The National Academy of Sciences (NAS) is praising EPA's efforts to improve its influential but controversial risk analysis program, the Integrated Risk Information System (IRIS), and even backs supporters' efforts to keep Republicans from consolidating the program with EPA's toxics office, underscoring steps Congress took in EPA's recent budget bill.

The new findings from an NAS panel, released April 11, mark a significant change for the program in the Trump administration. IRIS has faced years of critical reviews from NAS and others, and more recently, calls from industry representatives and GOP lawmakers to scale back the program.

“Overall, the committee was impressed with the changes being instituted in the IRIS program since” NAS' last IRIS review, published in 2014. “The committee views the transformation of the IRIS program as a work in progress, recognizes that this review assesses one moment in time in a still-evolving program, and acknowledges that the IRIS program will (and should) continue to evolve as it adapts and applies new scientific approaches and knowledge,” NAS' April 11 report states.

The new report, “Progress Toward Transforming the [IRIS] Program: A 2018 Evaluation,” follows EPA's request for NAS to review IRIS for the third time in seven years, as the new IRIS leaders, who took up their roles in the latter days of the Obama EPA, have proposed significant changes.

EPA sought a rapid review from NAS -- beginning in February with a two-day public workshop and concluding in NAS' release of the report April 11. The report's conclusions are not surprising; NAS' 2014 review was similarly positive, and the latest review has been viewed as an effort to bolster support for a program seen in the cross-hairs of Trump administration and Republican efforts to overhaul EPA.

EPA's IRIS program is widely influential, with its toxicity values used by EPA and other federal and state agencies, as well as internationally and across environmental media. But the program's efforts to be health protective have led to repeated criticism from regulated entities -- industry and other agencies like the Defense Department -- charging that the IRIS program produces overly-stringent risk analyses.

Such groups have closely followed EPA's efforts to reform the IRIS program following NAS' critical 2011 review of the draft IRIS assessment of formaldehyde, which included a rare extra chapter outside its charge which recommended a broad overhaul of the program.

Critics' efforts to end IRIS came to a head in proposed language in 2018 draft funding bills -- with one directing EPA to defund the program and the other directing EPA to consolidate the IRIS program with the nascent risk assessment division in EPA's toxics office, which is tasked with implementing the revised Toxic Substances Control Act (TSCA).

Neither proposal was adopted. Instead, the omnibus spending bill that Congress approved and President Donald Trump signed echoed the findings of the NAS panel by “encouraging” EPA to continue its reforms.

Systematic Review

Key among the reforms the agency is adopting is the use of systematic review, an approach adopted from medical research that seeks to provide a structured and documented process for transparent literature review and evaluation of the body of information.

The approach has been strongly recommended in past NAS reports, a point the latest report cites to push back against calls from some in Congress to move the program from EPA's research office into its emerging TSCA program because it would undermine the program's independence.

NAS' new report states that “current best practices recommended by” NAS' sister National Academy of Medicine for systematic review “suggest that the IRIS teams involved in the systematic-review process should be independent of those involved in regulatory decision-making who use the products of the systematic-review teams. The committee notes that the current organizational structure of the IRIS program in the EPA Office of Research and Development is consistent with those best practices.”

The report also praises the efforts of IRIS' new leaders, director Kris Thayer and Tina Bahadori, director of EPA's National Center for Environmental Assessment (NCEA), which oversees IRIS. “The change in NCEA and IRIS leadership has led to substantive reforms,” the report states.

The report also backs a controversial change Bahadori announced for IRIS last fall, when she proposed shifting the program to a “portfolio approach,” where its assessments would consider only those aspects most important to the agency office requesting the assessment -- such as an oral assessment only, or just looking at non-cancer toxicity -- rather than IRIS' traditional approach of providing risk estimates for as many endpoints as possible for both oral and inhalation exposure routes.

Bahadori acknowledged the change is controversial within EPA, but argued that it is necessary to make IRIS more efficient and to help the program produce more assessments. IRIS' limited output has long been an area of concern for stakeholders and reviewers.

“The move toward a portfolio approach appears to add need-based and context-based flexibility to the IRIS program,” the report states, pointing to the example of a new assessment of chloroform IRIS announced it was undertaking last fall focusing on non-cancer inhalation risk.

“The decision to limit the assessment was based on consultation with EPA regulatory programs. Overall, the portfolio approach is expected to conserve agency resources, and it is consistent with the recommendations of the National Academies report, *Science and Decisions: Advancing Risk Assessment* (NRC 2009).”

In one area that could prove controversial, the NAS committee, like Congress, recommends that the program release -- after public and peer reviews -- a handbook on how assessments are crafted.

But the report has yet to be finalized, and Bahadori in her remarks at the latest NAS committee's February workshop said that her priority is to produce new IRIS assessments, not write more policies.

“Changes in some of the critical elements of the overall IRIS process are still in progress. . . . EPA indicated that the handbook is still in development and is 'being updated to reflect Agency input, evolving IRIS practices.' Public release is anticipated in 2018. The handbook is expected to provide critical guidance for the development of IRIS assessments, and the present committee urges that high priority be given to its completion, peer review, and release.”

Still, the committee writes that it was “impressed by the overall enthusiasm displayed by EPA staff” at the February workshop “and the substantive progress toward full implementation of systematic review and transparency in IRIS assessments. The committee fully appreciates that changing the process and implementing systematic-review procedures while producing final assessments is a huge challenge for any organization, especially in such a short period (12 months) and with a shrinking staff.” -- Maria Hegstad (mhegstad@iwpnews.com)

Vicki Soto | 202-564-3077 | soto.vicki@epa.gov
ORD/NCEA/IRISD

Mailing Address:
USEPA Headquarters | William Jefferson Clinton Building | 1200 Pennsylvania Avenue, N.W. | MC: 8602R |
Washington, DC 20460

Delivery Address:
USEPA Headquarters | William Jefferson Clinton Building | 1300 Pennsylvania Avenue, N.W. | MC: 8602R |
Washington, DC 20460